

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

ACTELION PHARMACEUTICALS LTD and  
NIPPON SHINYAKU CO., LTD.

Plaintiffs,

v.

ZYDUS WORLDWIDE DMCC and ZYDUS  
PHARMACEUTICALS (USA) INC.,

Defendants.

Civil Action No. 1:20-03859  
(RMB)(SAK)

(Filed Electronically)

**CONSENT JUDGMENT AND ORDER OF PERMANENT INJUNCTION**

Plaintiffs Actelion Pharmaceuticals Ltd (“Actelion”) and Nippon Shinyaku Co., Ltd. (“Nippon Shinyaku”) (collectively, “Plaintiffs”) and Defendants Zydus Worldwide DMCC (“Zydus Worldwide”) and Zydus Pharmaceuticals (USA) Inc. (“Zydus USA”) (collectively, “Defendants” or “Zydus”) (collectively, the “Parties”), by their respective undersigned attorneys, hereby stipulate and consent to entry of judgment and injunction in this action as follows:

IT IS, this 14<sup>th</sup> day of January, 2022

HEREBY ORDERED, ADJUDGED AND DECREED that:

1. For purposes of this action only, this Court has jurisdiction over the subject matter of the above action and has personal jurisdiction over the Parties.

2. As used in this Consent Judgment and Order of Permanent Injunction, (i) the term “the ’302 Patent” means U.S. Patent No. 7,205,302, which Zydus agrees is valid and enforceable, (ii) the term “Zydus’s ANDA Products” means the products described in Abbreviated New Drug Application (“ANDA”) No. 214302 (“Zydus’s ANDA”), namely 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1000 mcg, 1200 mcg, 1400 mcg, and 1600 mcg selezipag

tablets as a generic version of Uptravi® as existing on the date of entry of this Consent Judgment, and as amended or supplemented from time to time in the ordinary course of business, (iii) the term “Affiliate” shall mean any entity controlling, controlled by, or under common control with a Party, but only as long as such control continues, where “control” means: (1) the ownership of at least fifty percent (50%) of the equity or beneficial interest of such entity, or the right to vote for or appoint a majority of the board of directors or other governing body of such entity; or (2) the power to directly, or indirectly direct or cause the direction of the management and policies of such entity by any means whatsoever.

3. Unless otherwise authorized by Plaintiffs, Zydus, including any of its successors and assigns, is enjoined from making, using, selling or offering to sell in, or importing into, the United States Zydus’s ANDA Products, on its own part or through any Affiliate, officer, agent, servant, employee or attorney, or through any person in concert or coordination with Zydus or its Affiliates, through and until after the later of (a) October 31, 2026, or (b) the last day of any period of pediatric exclusivity that is or may become associated with the ’302 Patent.

4. The Parties agree that jurisdiction and venue for an action to enforce performance under this Consent Judgment and Order of Permanent Injunction, including for a preliminary injunction against the breaching conduct, exists in this District Court, and the Parties hereby waive any and all defenses based on personal jurisdiction and venue.

5. This Court retains jurisdiction to enforce or supervise performance under this Consent Judgment and Order of Permanent Injunction.

6. The Complaint and all remaining claims, counterclaims, or affirmative defenses in the above action are dismissed without prejudice and without costs, disbursements, or attorney fees to any party.

**IT IS SO STIPULATED:**

By:

s/ Keith J. Miller


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*Attorneys for Defendants  
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Zydus Pharmaceuticals (USA) Inc.*

**SO ORDERED:**

This 14<sup>th</sup> day of January, 2022

  
HONORABLE RENEE M. BUMB  
UNITED STATES DISTRICT JUDGE